38. The method of claim 36, wherein the cancer is ovarian cancer.

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39. The method of claim 36, wherein the cancer is pancreatic cancer.

40. The method of claim 36, wherein the cancer is gastric cancer.

REMARKS

This is in response to the Official Action mailed October 11, 2002 for the above-referenced application. Applicants request an extension of time sufficient to make this paper timely, and enclose the appropriate fee.

Reconsideration of the application in view of the following remarks is respectfully requested.

Claims 36-40 have been added. Claims 1, 2, 6, 7 and 12-40 are pending in this application.

The Examiner rejected the pending claims under 35 USC § 112, second paragraph, as indefinite. Applicants respectfully traverse this rejection. In order to support a rejection under 35 USC § 112, it is the Examiner's burden to state why a person skilled in the art would be unable to understand the scope of the claim when it is read in light of the specification. *Ex Parte Cordova*, 10 U.S.P.Q. 2d 1949, 1952 (POBAI 1989). This burden is not met merely by stating that the claim may encompass several different embodiments, in the absence of any argument or reasoning that such a scope is inconsistent. Stated differently, the fact that a claim may be broad such that it encompasses several embodiments is not a basis to reject that claim as indefinite. *In re Skoll*, 187 U.S.P.Q. 481 (C.C.P.A. 1975)(claim reciting organic and inorganic acids found to be broad, not indefinite).

With respect to the Examiner's remarks concerning claims 12 and 26-30 in which he implies that destroying cells in a petri would not accomplish anything (thus raising a specter of a

utility rejection), Applicants point out that destroying cancerous cells *ex vivo* (including in a petri dish) may be desirable where material is removed from a patient, treated and later returned.

The Examiner has rejected method claims 13-17 and 31-35 under 35 USC § 112, first paragraph. The basis for this rejection is the Examiner's statement that the claims "are drawn to the treatment of cancer generally," and his unsupported assertion that "no compound has ever been found that can treat cancers generally." The basis for this argument is largely that the Examiner is classing cancer therapy with perpetual motion machines and assumes in assessing enablement that it is inherently unbelievable that a cancer therapy could work generally. Such may have been the case when *In re Buting* was decided in 1969, but the art and the law have progressed since then. The notion of automatic unbelievability is no longer credited. Indeed, as the Board of Appeal noted in 1987 in *Ex parte Rubin*, 5 USPQ2d 1461, 1462 (POBAI 1987), "'contemporary knowledge in the art' has far advanced since the days when the any statement of utility in treating cancer was per se 'incredible.'" Here, the Examiner has not offered any reasoning as to why the assertions of general utility in this application, given the suggested mechanism of action. As such, the Examiner has failed to meet the burden discussed in *In re Marzocchi*, 169 USPQ 367, 369 (CCPA 1971), where it is noted that:

> a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond to those used in describing and defining the subject matter sought to be patents *must* be taken as in compliance with the enabling requirement of the first paragraph of § 112, *unless* there is a reason to doubt the objective truth of the statements contained therein, which must be relied upon for an enabling disclosure.

A thirty-year-old case discussing the state of the art at that time, is not a reason to doubt the truth of the asserted utility here.

Furthermore, Applicants have submitted evidence in Serial No. 09/937,192 showing that a monomeric ansamycin compound, 17-allylamino-geldanamycin (17-AAG), which is mentioned in the specification on Page 8, line 15 and other hsp90 inhibitors are efficacious in a variety of tumor types including breast cancer, ovarian cancer, pancreatic cancer and gastric cancer (the

cancer types specifically mentioned on Page 8, lines 9-11 of the application), other HER kinase overexpressing tumors, and tumors which do not over express HER kinase. For example, Yang et al. (Exhibit A), report inhibition of glioma (brain tumor) cells with 17-AAG. Okabe et al. (Exhibit B) reports *in vivo* activity of herbimycin A (an ansamycin antibiotic) against leukemia cells. Kelland *et al* (Exhibit C, JNCI 91: 1940, 1999) achieved tumor cytostasis in two human colorectal carcinomas, HT29 and BE for the duration of drug treatment with 17-AAG. Burger *et al* (Exhibit D Proc. AACR, 41: Abstract # 2844, 2000) reported potent effects of 17-AAG against a melanoma xenograft and, interestingly, preliminary data from the London arm of the 17-AAG trial indicates that melanoma (2/6 objective responses) may be a responsive tumor (Exhibit E Banerji *et al*, Proc. ASCO, Abstract # 326, 2001) 17-AAG has also been used in studies with prostate cancers, and it has been shown that this administration resulted in dose-dependent inhibition of androgen-dependent and -independent prostate cancer xenografts. (Exhibit F Solit et al., *Clin. Cancer Res.* 8: 986-993, 2002). 17-AAG has also been shown to enhance paclitaxel-mediated cytotoxicity in lung cancer cells (Exhibit G Nguyen et al, *Ann. Thorac. Surg.* 72: 371-379, 2001); and to modulate metastasis phenotypes in non-small cell lung cancer (Exhibit H Nguyen et al., *Ann. Thorac. Surg.* 70: 1853-60, 2000). Thus, the efficacy of compounds that bind to the hsp90 receptor span a wide range of unrelated cancers, thereby refuting the Examiner's statement that generalized cancer therapy is inherently unbelievable.

For the foregoing reasons, Applicants submit that the current claims are in form for allowance. Favorable reconsideration and allowance of all claims are respectfully urged.

Respectfully submitted,

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